



Whitehall-Robins
Five Giralda Farms
Madison, NJ 07940-0871
Telephone (973) 660-5500
Website address: <http://healthfront.com>

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June 25, 1999



Caltrate® PLUS

Notification of Statements on Dietary Supplement Labels

Elizabeth A. Yetley, Ph.D., R.D., Director
Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW
Washington, D.C. 20204

Dear Dr. Yetley:

Reference is made to Caltrate® PLUS, marketed by Whitehall-Robins Healthcare ("Whitehall-Robins"), a division of American Home Products Corporation.

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, as codified in 21 U.S.C. §343(r)(6), notification is submitted for structure/function statements made on the following dietary supplement product.

Product Name: Caltrate PLUS

Ingredients: Calcium Carbonate, Vitamin D, Magnesium, Zinc, Copper, Manganese, Boron

Company Name/ Whitehall-Robins Healthcare
Address: Five Giralda Farms
Madison, New Jersey 07940

Statements on the Label:

Side Panel of Label

- Each tablet provides more calcium for your bones than any leading brand.*
- Caltrate 600 PLUS also contains these six additional fortifying nutrients essential for healthy bone formation.*

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LET 3892

- Magnesium – Important for maintaining strong bones.*
- Zinc, Copper, Manganese – Essential for skeletal development.*

In accord with 21 CFR §101.93, the disclaimer statement is **bolded** and boxed on the panel of the carton where **structure/function** claims appear.

Additionally, the back panel of the label contains the health claim “may reduce the risk of osteoporosis” with all required information for use of such claim.

The undersigned certifies that the information contained in this notice is complete and accurate, and that Whitehall-Robins has substantiation that the statements made are truthful and not misleading.

As required, the original and two copies of this notification are enclosed. If you have any questions regarding this information, please contact the undersigned at (973) 660-5751.

Sincerely,

WHITEHALL-ROBINS HEALTHCARE



Eleanor F. Barbo
Senior Director
Regulatory Affairs